

REMARKS

The Office Action dated August 11, 2004, has been carefully reviewed and the foregoing amendment has been made in response thereto. Claims 20-23 have been added. Claims 1-6, and 18-23 are pending in the application. Claims 2 and 3 are currently withdrawn from consideration.

The rejection of claims 1, 4-6, 18 and 19 under 35 USC 102(b) as being anticipated by Dye et al is respectfully traversed. Claims 1 and 5 relate to a retrograde cannula for delivering fluid to a patient's vessel (specifically delivering cardioplegia to a heart vessel in claim 5). The cannula body includes a passage arrangement fluidly communicating the balloon with the infusion lumen to enable the balloon to be inflated by the pressurized fluid (e.g., cardioplegia in claim 5) being conducted through the infusion lumen and through the lumen outlet. The passage arrangement is the sole means of delivering inflation fluid to the balloon -- thus, one lumen provides both the fluid being delivered to the patient's vessel and the fluid for inflating the balloon, thereby simplifying the cannula and minimizing its size. Loss of fluid pressure in the inflated balloon is prevented by a valve for opening and closing the passage arrangement until deflation is desired.

Dye et al fails to either teach or suggest the claimed cannula. Dye et al discloses a catheter for draining a body cavity (specifically, the urethra). Inflation of the retention balloon in Dye et al requires a dedicated inflation lumen 32 which runs the length of the catheter along with a drainage lumen 28. Only drainage lumen 28 in Dye et al communicates with the patient's body. Thus, there is no single lumen in Dye et al that delivers fluid to both a patient's vessel and an inflatable balloon in parallel, and Dye et al fails to disclose the structure recited in claim 1.

Apparently, the rejection attempts to read the infusion lumen of claims 1 and 5 on drainage lumen 28 of Dye et al. This, however, would make Dye et al inoperative because the fluid in the drainage lumen cannot be used to inflate the balloon for several reasons. The flap valve 60 between balloon 30 and drain lumen 28 is openable only when the catheter is being removed from the patient, i.e., at the time

that the balloon must be deflated. Flap valve 60 acts as a one-way valve which only allows fluid to flow out of the balloon (Dye et al uses a separate lumen to inflate it). When draining the bladder or urethra, the bodily fluid is prevented from entering the balloon by the operative structure of flap valve 60. If, contrary to the teaching of Dye et al, one were to introduce pressurized fluid into the proximal end of drain lumen 28 in order to deliver the fluid to the patient's body then the pressurized fluid still would not inflate the balloon. Thus, claims 1, 4-6, 18, and 19 are allowable over Dye et al.

The rejection of claims 1, 4-6, 18 and 19 under 35 USC 102(b) as being anticipated by Finney is respectfully traversed. Finney discloses an interior tube C and an exterior tube D. The lumen space between the tubes is used to inflate the balloon, and the drain lumen in the interior of tube C communicates with the urethra for draining. Thus, Finney lacks the infusion lumen recited in claims 1 and 5. If the catheter in Finney is used to inject a medicated or other liquid, it is injected through valve d (i.e., it is first injected in the balloon and then released from the balloon into the patient through aperture f controlled by valve d). Thus, the balloon in Finney is deflated when delivering fluid to the patient. The balloon of the present invention remains inflated whether or not fluid is delivered to the vessel. Not only is Finney structurally different, it could not be used in the manner of the claimed retrograde cannula. Therefore, claims 1, 4-6, 18, and 19 are allowable over Finney.

The rejection of claims 1, 4-6, 18 and 19 under 35 USC 102(b) as being anticipated by Lafontaine et al is respectfully traversed. Lafontaine et al completely lacks any teaching or any capacity to infuse fluid into a patient's vessel. A guide wire tube 52 passes through balloon 53a. Prior to use in vivo, the balloon may be primed with a small amount of fluid through a one-way valve 51 by using a balloon protector 53b (to prevent actual inflation) and a connector 57 (to supply a pressurized fluid at the distal end before insertion of the catheter into a patient). The protector and connector cannot be present during use in vivo. Once inserted into a patient, the Lafontaine et al catheter is a closed fluid system. During angioplasty, the balloon is inflated by a fluid bolus 18 via shaft 41a. None of the fluid is capable of being

delivered to the patient's vessel. Therefore, claims 1, 4-6, 18, and 19 are allowable over Lafontaine et al.

The rejection of claims 1, 4-6, 18 and 19 under 35 USC 102(b) as being anticipated by DiCaprio et al is respectfully traversed. DiCaprio is another example of the use of a guide wire lumen 32 to preload a balloon 22 with fluid prior to insertion into a patient. A separate inflation lumen 28 provides inflation fluid to balloon 22 during use. DiCaprio et al fails to either teach or suggest a passage as the sole means of delivering inflation fluid to the balloon. In view of the structural differences, DiCaprio et al likewise cannot be used in the manner of the present invention. Therefore, claims 1, 4-6, 18, and 19 are allowable over DiCaprio et al.

New claims 20-23 likewise are distinguishable from all the prior art of record. None of the prior art discloses or suggests a valve wherein a portion of the fluid delivered to the distal end of the infusion lumen enters and inflates the inflatable balloon when the valve is open and the fluid is flowing through the infusion lumen, and wherein any fluid having passed into the inflatable balloon is trapped therein when the valve is closed regardless of fluid then flowing in the infusion lumen.

Since generic claims 1 and 5 are allowable, dependent claims 2 and 3 should be considered and allowed.

In view of the foregoing amendment and remarks, claims 1-6 and 18-23 are now in condition for allowance. Favorable action is respectfully solicited.

Respectfully submitted,



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